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§19–120.1.

- (a) (1) In this section the following words have the meanings indicated.
- (2) “Certificate of conformance” means an approval issued by the Commission that allows an acute general hospital to establish emergency PCI services or elective PCI services without a certificate of need.
- (3) “Certificate of ongoing performance” means an approval issued by the Commission that the cardiac surgery services, emergency PCI services, or elective PCI services provided by an acute general hospital meet standards evidencing continued quality.
- (4) “Elective PCI” (also known as “nonprimary PCI”) includes PCI provided to a patient who is not suffering from an acute coronary syndrome, but whose condition is appropriately treated with PCI based on regulations established by the Commission.
- (5) “Emergency PCI” (also known as “primary PCI”) includes PCI capable of relieving coronary vessel narrowing associated with STEMI or, as defined by the Commission in regulations, STEMI equivalent.
- (6) “PCI” means percutaneous coronary intervention.
- (7) (i) “Percutaneous coronary intervention” means a procedure in which a catheter is inserted into a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing.
- (ii) “Percutaneous coronary intervention” includes a variety of catheter-based techniques, including balloon angioplasty.
- (8) “STEMI” (ST–segment–elevation myocardial infarction) means a type of heart attack or myocardial infarction that is caused by a prolonged period of blocked blood supply, which affects a large area of the heart muscle and causes changes on an electrocardiogram and in the blood levels of key chemical markers.
- (b) (1) Beginning July 1, 2012, before an acute general hospital may establish emergency PCI services or elective PCI services, the hospital shall obtain a certificate of conformance from the Commission.

(2) The Commission may not issue a certificate of conformance unless the Commission finds that the proposed emergency PCI services or proposed elective PCI services:

(i) Are consistent with the State Health Plan for Facilities and Services;

(ii) Will result in the delivery of more efficient and effective health care services; and

(iii) Are in the public interest.

(c) Notwithstanding subsection (b) of this section, a certificate of conformance is not required for an acute general hospital to establish emergency PCI services if:

(1) The acute general hospital was providing emergency PCI services on January 1, 2012; and

(2) The Commission determines that the emergency PCI services are consistent with the State Health Plan for Facilities and Services.

(d) Notwithstanding subsection (b) of this section, a certificate of conformance is not required for an acute general hospital to establish elective PCI services if:

(1) On January 1, 2012, the acute general hospital was providing elective PCI services through the C-PORT E registry under authority of a research waiver issued by the Commission;

(2) The Commission finds that the C-PORT E study produced results that should guide public policy; and

(3) The Commission determines that the elective PCI services provided by the acute general hospital continue to be consistent with:

(i) The requirements of the C-PORT E registry; and

(ii) Except for the requirements under COMAR 10.24.05.05, the requirements for maintaining a research waiver under COMAR 10.24.05 and 10.24.17, Table A-1.

(e) (1) This subsection applies to an acute general hospital that provides cardiac surgery or PCI services under:

- (i) A certificate of need issued under § 19–120 of this subtitle;
- (ii) A certificate of conformance issued under this section; or
- (iii) An exception from the certificate of conformance requirements under subsection (c) or (d) of this section.

(2) An acute general hospital shall obtain and maintain a certificate of ongoing performance to continue to provide:

- (i) Cardiac surgery services;
- (ii) Emergency PCI services; or
- (iii) Elective PCI services.

(f) An acute general hospital that is providing elective PCI services under a research waiver issued by the Commission and does not meet the requirements of subsection (d) of this section shall obtain a certificate of conformance for its elective PCI services before the acute general hospital may obtain a certificate of ongoing performance to provide the elective PCI services.

(g) (1) The Commission shall adopt regulations through an update to the State Health Plan for Facilities and Services to implement this section.

(2) The regulations shall:

- (i) Address quality, access, and cost;
- (ii) Establish a process and minimum standards for obtaining a certificate of conformance;
- (iii) Establish a process and minimum standards for obtaining and maintaining a certificate of ongoing performance;
- (iv) Set an appropriate time period for the expiration of a certificate of ongoing performance;
- (v) Require, as a condition of the issuance of a certificate of conformance or a certificate of ongoing performance, that an acute general hospital agree to voluntarily relinquish its authority to provide cardiac surgery services, emergency PCI services, or elective PCI services if the hospital fails to meet the applicable standards established by the Commission;

(vi) Establish a process for an acute general hospital that is out of compliance with minimum standards for a certificate of ongoing performance to return to good standing;

(vii) Require that an acute general hospital, except for an acute general hospital located in a part of the State that does not have sufficient access to emergency PCI services, have provided emergency PCI services in accordance with established standards before seeking a certificate of conformance for elective PCI services;

(viii) Prohibit an acute general hospital from providing elective PCI services unless the acute general hospital also provides emergency PCI services;

(ix) Incorporate, to the extent appropriate, the standards for cardiac surgery services, emergency PCI services, and elective PCI services recommended by the clinical advisory group established under paragraph (3) of this subsection;

(x) Include requirements for peer or independent review, consistent with the ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention (Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions), of difficult or complicated cases and for randomly selected cases; and

(xi) For a certificate of conformance for elective PCI services, give weight to the experience, performance, investment, and scope of interventional capabilities of an applicant hospital that was providing emergency PCI services on January 1, 2012.

(3) (i) The Commission shall establish a clinical advisory group to advise the Commission and recommend standards for cardiac surgery services, emergency PCI services, and elective PCI services for inclusion in regulations adopted under this subsection.

(ii) The clinical advisory group shall be composed of experts in cardiac surgery services and PCI services, including:

1. Clinicians and representatives from hospitals in the State with and without on-site cardiac surgery services and with and without PCI services;

2. At least one representative of an acute general hospital that is not part of a merged asset system and provides only emergency PCI services; and

3. Other persons with needed expertise from inside and outside the State.

(4) (i) On or before September 30, 2013, after obtaining advice from the clinical advisory group and other appropriate stakeholders, the Commission shall:

1. Develop recommended regulations under this subsection;

2. Post the recommended regulations on its website for public comment; and

3. Submit the recommended regulations to the Governor and, in accordance with § 2–1257 of the State Government Article, the Senate Finance Committee and the House Health and Government Operations Committee.

(ii) The Senate Finance Committee and the House Health and Government Operations Committee shall have 60 days from receipt of the recommended regulations for review and comment.

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